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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/552,074

11/17/2005

Raymond Glocker

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8800

23117

7590

04/27/2009

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EXAMINER

DOUGHERTY, SEAN PATRICK

ART UNIT

PAPER NUMBER

3736

MAIL DATE

DELIVERY MODE

04/27/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/552,074	Applicant(s) GLOCKER ET AL.	
	Examiner SEAN P. DOUGHERTY	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02/04/2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on (none filed) is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This is the initial Office action after RCE based on the 10/552074 application filed 11/17/2005. Claims 1-10 and 12-20 are currently pending and have been considered below.

Priority

This application's claim of being a 371 of PCT/CH03/00227, filed 04/08/2003, is acknowledged by Examiner. Certified copies of the priority documents have been received in from the International Bureau (PCT Rule 17.2(a)). Claim to priority should be listed in the first lines of the specification.

Response to Amendment

The amendments filed 02/04/2009 have been considered by Examiner.

Examiner acknowledges the amendments to claims 1, 10, 12, 13, 19 and 20 and cancelled claim 11 are acknowledged.

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Drawings

The subject matter of this application admits of illustration by a drawing to facilitate understanding of the invention. Applicant is required to furnish a drawing under 37 CFR 1.81(c). No new matter may be introduced in the required drawing. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 13-20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 13 positively recites limitations that overlap statutory classes. In this case, the applicant has positively recited a method and an apparatus in the same claim. See MPEP 2173.05(p) II.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-10 and 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,450,972 to Knoll in view of US 5,433,708 to Nicholas et al. (Nicholas). Knoll discloses a method for performing pressure measurements in a mammal body tracts or cavities or blood vessels by means of a pressure profile sensors technique (abstract, lines 5-7; col. 1, lines 4-10), which comprises introducing into the mammal a single lumen (Fig. 8) innocuous polymer catheter (col. 2, lines 5-7) having at least a portion of its wall which is sufficiently flexible to be deflected by external pressure (col. 1, lines 30-38), introducing progressively step-by-step into the catheter lumen an electrically conductive aqueous liquid substance (such as saline, col. 5, lines 20-21) while applying simultaneously the electrically conductive liquid substance an low voltage and high frequency alternative current between 500 mV and 6V or 60 and 130 kHz (col. 2, line 2) and mechanical movement (col. 1, lines 47-64; abstract, lines 2), detecting by means of an electrode 21 placed at the external surface of the subject the current induced by the liquid substance traveling through the catheter (col. 1, line 65 to col. 2, line 2), transferring the current thus recorded to a converter suitable to convert the current parameters provided thereto into corresponding pressure values (col. 5,

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lines 13-25; col. 1, lines 65 to col. 2, line 2), e) displaying the pressure values as such, or as a function of the measurement location or measurement period or both to afford corresponding pressure profiles at a time and different from that of the leakage current thus recorded (Figures 1a-1c; col. 7, lines 3-16). Note that it is and old and well know technique to one of ordinary skill in the art to display results of a measurement; results are generally displayed for analysis during a procedure and similarly, stored and displayed after a procedure for additional analysis. Therefore, a skilled artisan would have found displaying the pressure data of Knoll on a display at a time different from when the pressure measurements are taken since such practice as obvious. Knoll does not expressly disclose applying mechanical oscillations that have a controlled amplitude and frequency to the electrically conductive substance nor does Knoll expressly disclose a leakage current.

Nicholas is a reference in analogous art that discloses a medical instrument for introduction into a living mammal to perform a medical operation. The medical instrument induces an oscillating flow of a fluid inside the medical device (col. 1, lines 15-17), the oscillation having a controlled amplitude and frequency (col. 11, lines 51-54) by way of a peristaltic pump 74. One having an ordinary skill in the art at the time the invention was made would have found it obvious to modify the liquid of Knoll to be oscillated by way of the controlled amplitude and frequency technique using the peristaltic pump 74 of Nicholas, since the predictable result of oscillating fluid flow within the catheter of Knoll would ensue. Therefore, a skilled artisan would have found the combination of Knoll and Nicholas obvious.

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Additionally, one having an ordinary skill in the art at the time the invention was made would have found the usage of a leakage current to perform a pressure measurement obvious because Knoll establishes that a current may be used to detect a pressure profile (col. 1, line 65 to col. 2, line 2). As admitted by Applicant in paragraph 7 of the affidavit, "a current, i.e. leakage current, is therefore generated". It appears that Applicant has equated a leakage current to simply be a current. This admission is further established on page 3 where the Applicant cites a passage from Wikipedia that establishes that a leakage current is simply a current that slowly discharges the capacitor. As best understood by Examiner based on the provided affidavit, it appears that Applicant intends to establish a leakage current to be where a current is no longer desired within the catheter system and the current is desired to be "turned off". When the current is turned off, a current at a lower value (leakage current) leaks due to an imperfect dielectric material. However, there is no evidence in the specification or claimed invention to suggest that a leakage current is anything different from a current.

Examiner notes it is also possible a leakage current may still occur when the device of Knoll is in operation and a current is induced through the saline solution since the capacitor is still being discharged. While not expressly stated, a leakage current may be read alongside the current measurement because the capacitor may include unintended current which may be considered a leakage current.

Lastly, one having an ordinary skill in the art at the time the invention was made would have found it obvious to use the device of Knoll to measure a pressure profile when a current is not intended to be induced through the saline solution and leakage

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current occurs. A skilled artisan would understand that the device of Knoll would have a "leakage current" when no current is being applied because the capacitor of the system would leak current into the saline solution due to imperfections of dielectric materials. Since the system of Knoll measures current, it would also be capable of measuring the leakage current provided by the capacitor. The device of Knoll in view of Nicholas provides a device that would be obvious to perform a pressure profile measurement based on a leakage current that a skilled artisan would find obvious within the saline solution provided by the capacitor of Knoll.

Regarding claims 9 and 14, Knoll does not appear to explicitly disclose a method wherein the mechanical oscillations applied to the electrically conductive liquid substance have a maximum amplitude of about 2/4mm and a maximum frequency of about 10/15 Hz. However, Nichols et al. teaches a method wherein the mechanical oscillations applied to the electrically conductive liquid substance have a maximum amplitude of about 2/4mm and a maximum frequency of about 10/15 Hz ("aspirating and expelling relatively small volumes of ... medium through the catheter, typically in the range from about 0.1 ml to 3 ml" col. 3 lines 63-68; "catheters having diameters in the range from about 1.5 mm to 3 mm" col. 10 lines 32-34; "oscillation will typically be performed at from about 0.1 Hz to 5 Hz" col. 3 line 67-68).

Knoll and Nichols et al. are analogous art because they are from the same field of endeavor/problem solving area medical instruments, particularly catheters placed in a living mammal to perform a medical operation. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Knoll and

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Nichols et al. before him or her to modify the fluid flow of Knoll to have the amplitude of about max. 2/4 mm and a frequency of about max 10/15 Hz of Nicholas et al.; this is simply applying a known technique of applying mechanical oscillation means connected downwards to a peristaltic pump to a known device ready for improvement being an apparatus for performing pressure measurements, to yield the predictable result of the electroconductive liquid oscillating in movement when entering the lumen of the catheter. The motivation for doing so would have been “to realize a measurement system in which a pressure profile can be measured” as disclosed by Knoll (col. 1 lines 25-27) and to provide a “method for inducing an oscillating flow of ... fluid” (col. 1 lines 16-17) as taught by Nichols et al. Therefore, a skilled artisan would have found the combination of Knoll and Nicholas obvious.

Response to Affidavit under 37 CFR 1.132

The affidavit under 37 CFR 1.132, filed 02/04/2009, is insufficient to overcome the rejection of claims 1-20 based upon the rejection that has not been overcome as set forth in the last Office action because the affidavit fails to set forth facts from a reliable source. It is Examiner respectful contention that the cited portions of Wikipedia do not constitute a reliable source with consistent facts. Examiner notes that generally, affidavit evidence is provided by citing patents/publications, books, encyclopedias and scholarly articles that have been subject to edit and review by independent parties. Since Wikipedia can be edited by anyone with an internet connect, it is subject to changes and entries by any individual leading to the possibility of incorrect and falsified entries. While

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the provided evidences has been thoroughly considered by Examiner, the evidence remains insufficient to overcome the rejection of the claims in the previous Office action and in the present Office action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN P. DOUGHERTY whose telephone number is (571)270-5044. The examiner can normally be reached on Monday-Friday, 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean P. Dougherty/
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736